



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0762]

### Revocation of Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of 15 Emergency Use Authorizations (EUAs) (the Authorizations), including 12 Authorizations for decontamination systems for personal protective equipment, 1 Authorization for a bioburden reduction system for personal protective equipment, and 2 umbrella Authorizations for certain imported, non-NIOSH (National Institute of Occupational Safety and Health)-approved disposable respirators. FDA revoked the Authorizations for the decontamination and bioburden reduction systems for personal protective equipment on June 30, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each Authorization holder. FDA revoked the umbrella Authorizations issued to manufacturers and other stakeholders of imported non-NIOSH approved filtering facepiece respirators manufactured in China (China FFR Authorization), and to manufacturers and other stakeholders of imported non-NIOSH approved filtering facepiece respirators (Imports FFR Authorization) on June 30, 2021, under the FD&C Act. The revocations, which each include an explanation of the reasons for the revocation, are reprinted in this document.

DATES: The Authorizations for the decontamination and bioburden reduction systems are revoked as of June 30, 2021. The Authorizations for the China FFR Authorization and Imports FFR Authorization are revoked as of July 6, 2021.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. Notice of the issuance of the Authorizations was published in the *Federal Register* as follows, as required by section 564(h)(1) of the FD&C Act: (1) published June 5, 2020 (85 FR 34638) for Imports FFR Authorization (Certain Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators) issued March 24, 2020; China FFR Authorization (Certain Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China) issued April 3, 2020; and STERIS Corporation for the STERIS Sterilization Systems (STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems) issued April 9, 2020; (2) published July 14, 2020 (85 FR 42407) for Advanced Sterilization Products, Inc. for the ASP STERRAD Decontamination Systems issued April 11, 2020; Stryker Instruments for the STERIZONE VP4 Sterilizer issued April 14, 2020; Steriluent, Inc. for the Steriluent HC 80TT Hydrogen Peroxide Sterilizer issued April 20, 2020; Duke University Health System for the Duke

Decontamination System issued May 7, 2020; (3) published November 20, 2020, (85 FR 74346) for STERIS Corporation for the AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle issued May 21, 2020; Stryker Sustainability Solutions (SSS) for the SSS VHP N95 Respirator Decontamination System issued May 27, 2020; Technical Safety Services LLC for the 20-CS Decontamination System issued June 13, 2020; MSU for the MSU Decontamination System issued July 24, 2020; (4) published April 23, 2021, (86 FR 21749) for Roxby Development, LLC for the Zoe-Ann Decontamination System issued October 20, 2020; 3B Medical, Inc. for the Lumin LM3000 Bioburden Reduction UV System issued December 3, 2020; Ecolab Inc. for the Bioquell Technology System issued December 4, 2020; and Yale New Haven Health System for the Yale New Haven Health FILTERING FACEPIECE RESPIRATOR Decontamination System issued January 15, 2021.

Any subsequent reissuances of the Authorizations are listed in the revocation letters reprinted at the end of this document.

The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

## II. EUA Revocation Criteria Met

On June 30, 2021, FDA revoked the China FFR Authorization and Imports FFR Authorization. FDA reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations, FDA Imports database, healthcare organizations, and Federal/State stockpiles. Based on the change in the Centers for Disease Control and Prevention (CDC) recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare

organizations and others,<sup>1</sup> FDA has concluded that the known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the FD&C Act for issuance of the Authorizations are no longer met. In addition, based on the same information, revocation of the Authorizations is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the FD&C Act.

On June 30, 2021, FDA revoked the Authorizations for decontamination and bioburden reductions systems pursuant to requests from the following entities on the following dates:

- April 9, 2021, from Duke for the Duke Decontamination System;
- April 15, 2021, from Steriluent, Inc. for the Steriluent HC 80TT Hydrogen Peroxide Sterilizer;
- April 16, 2021, from Yale for the Yale New Haven Health FFR Decontamination System;
- May 13, 2021, from STERIS Corporation for the STERIS Sterilization Systems, as well as the AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle;
- May 25, 2021, from Stryker Sustainability Solutions (SSS) for the SSS VHP N95 Respirator Decontamination System;
- May 27, 2021 from MSU for the MSU Decontamination System;

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<sup>1</sup> Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for healthcare personnel (HCP). Available information now shows an increase in the current and projected U.S. supply of NIOSH-approved respirators, including N95s ([https://www.cdc.gov/niosh/npptl/topics/respirators/disp\\_part/N95list1.html](https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html)). As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP “transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s” (<https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-recommends-transition-use-non-niosh-approved-and-decontaminated-disposable-respirators>). In addition, on June 21, 2021 (86 FR 32376), OSHA issued an Emergency Temporary Standard (ETS) to adequately address the hazard of COVID-19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID-19.

- June 4, 2021, from Advanced Sterilization Products, Inc. for the ASP STERRAD Decontamination Systems;
- June 7, 2021, from Technical Safety Services LLC for the 20-CS Decontamination System;
- June 7, 2021, from Roxby Development, LLC for the Zoe-Ann Decontamination System;
- June 7, 2021, from 3B Medical, Inc. for the Lumin LM3000 Bioburden Reduction UV System;
- June 7, 2021, from Ecolab Inc. for the Bioquell Technology System; and
- June 8, 2021, from Stryker Instruments for the STERIZONE VP4 Sterilizer.

Because these entities notified FDA that they have ceased operations and associated activities and request withdrawal of their respective Authorizations, and consistent with FDA's belief that the known and potential benefits of these systems, when used for their emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke the Authorizations because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety.

### III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov/> and <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#covid19>

### IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(B) and 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the following Authorizations:

- China FFR Authorization;
- Imports FFR Authorization;
- Duke's Duke Decontamination System;
- Steriluent, Inc.'s Steriluent HC 80TT Hydrogen Peroxide Sterilizer;
- Yale's Yale New Haven Health FFR Decontamination System;
- STERIS Corporation's STERIS Sterilization Systems, as well as the AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle;
- Stryker Sustainability Solutions's SSS VHP N95 Respirator Decontamination System;
- MSU's MSU Decontamination System;
- Advanced Sterilization Products, Inc.'s ASP STERRAD Decontamination Systems;
- Technical Safety Services LLC's 20-CS Decontamination System;
- Roxby Development, LLC's Zoe-Ann Decontamination System;
- 3B Medical, Inc.'s Lumin LM3000 Bioburden Reduction UV System;
- Ecolab Inc.'s Bioquell Technology System; and
- Stryker Instruments's STERIZONE VP4 Sterilizer.

The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.



June 30, 2021

To: Manufacturers of Non-NIOSH Approved Filtering Facepiece Respirators Manufactured in China;  
Health Care Personnel;  
Hospital Purchasing Departments and Distributors;  
Importers and Commercial Wholesalers; and  
Any Other Stakeholders

This letter is to revoke the Emergency Use Authorization (EUA) issued April 3, 2020 and revised and reissued on May 7, 2020, June 6, 2020, and October 15, 2020, for emergency use of non-National Institute for Occupational Safety and Health (NIOSH) approved respirators manufactured in China<sup>1</sup> in healthcare settings by healthcare personnel (HCP)<sup>2</sup>, when used in accordance with Centers for Disease Control and Prevention (CDC) recommendations to prevent HCP exposure to pathogenic biological airborne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak. The revocation is effective July 6, 2021.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act).

FDA has reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations (GPOs), FDA Imports database, healthcare organizations, and federal/state stockpiles. Based on the change in CDC recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare organizations and others,<sup>3</sup> FDA has concluded that the

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<sup>1</sup> [Umbrella EUA: Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China](#)

<sup>2</sup> Healthcare personnel refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

<sup>3</sup> Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for HCP. Available information now shows an increase in the current and projected U.S. supply of [NIOSH-approved respirators, including N95s](#). As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP “transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s.” In addition, on June 21, 2021, OSHA issued an

known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the Act for issuance of the EUA are no longer met. In addition, based on the same information, revocation of the EUA is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2)(B) and 564(g)(2)(C) of the Act, FDA revokes the EUA.

Effective on July 6, 2021, which is 15 days after the effective date of the OSHA ETS, and the date by which compliance by healthcare facilities is required, the devices listed in Appendix A as covered by the October 15, 2020 EUA are not authorized by FDA for use as respirators in healthcare settings by HCP to prevent HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, and therefore cannot be legally introduced into interstate commerce with that intended use.

FDA encourages manufacturers and other stakeholders to inform their customers and HCP, as applicable, of this revocation. Manufacturers, HCP, hospital purchasing departments, distributors, importers, commercial wholesalers, states, and any other stakeholders who have questions about options to redistribute or recondition their supply of non-NIOSH-approved respirators that will not be authorized effective July 6, 2021, may reference the publicly posted frequently asked questions ([FAQ](#)) regarding this revocation letter or contact FDA at [CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov).

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

\_\_\_\_\_/s/\_\_\_\_\_  
RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

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[Emergency Temporary Standard \(ETS\)](#) to adequately address the hazard of COVID-19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID-19.





June 30, 2021

To: Manufacturers of Imported, Non-NIOSH Approved Filtering Facepiece Respirators;  
Health Care Personnel;  
Hospital Purchasing Departments and Distributors;  
Importers and Commercial Wholesalers; and  
Any Other Stakeholders

This letter is to revoke the Emergency Use Authorization (EUA) issued March 24, 2020 and revised and reissued on March 28, 2020, June 6, 2020, and March 24, 2021, for emergency use of imported non-National Institute for Occupational Safety and Health (NIOSH) approved respirators<sup>1</sup> in healthcare settings by healthcare personnel (HCP)<sup>2</sup>, when used in accordance with Centers for Disease Control and Prevention (CDC) recommendations to prevent HCP exposure to pathogenic biological airborne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak. The revocation is effective July 6, 2021.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act).

FDA has reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations (GPOs), FDA Imports database, healthcare organizations, and federal/state stockpiles. Based on the change in CDC recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare organizations and others,<sup>3</sup> FDA has concluded that the

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<sup>1</sup> [Umbrella EUA: Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators](#)

<sup>2</sup> Healthcare personnel refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

<sup>3</sup> Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for HCP. Available information now shows an increase in the current and projected U.S. supply of [NIOSH-approved respirators, including N95s](#). As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP "transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s." In addition, on June 21, 2021, OSHA issued an [Emergency Temporary Standard \(ETS\)](#) to adequately address the hazard of COVID-19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID-19.

known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the Act for issuance of the EUA are no longer met. In addition, based on the same information, revocation of the EUA is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2)(B) and 564(g)(2)(C) of the Act, FDA revokes the EUA.

Effective on July 6, 2021, which is 15 days after the effective date of the OSHA ETS, and the date by which compliance by healthcare facilities is required, the devices listed in Exhibit 1 as covered by the March 24, 2021 EUA are not authorized by FDA for use as respirators in healthcare settings by HCP to prevent HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, and therefore cannot be legally introduced into interstate commerce with that intended use.

FDA encourages manufacturers and other stakeholders to inform their customers and HCP, as applicable, of this revocation. Manufacturers, HCP, hospital purchasing departments, distributors, importers, commercial wholesalers, states, and any other stakeholders who have questions about options to redistribute or recondition their supply of non-NIOSH-approved respirators that will not be authorized effective July 6, 2021, may reference the publicly posted frequently asked questions ([FAQ](#)) regarding this revocation letter or contact FDA at [CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov).

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

\_\_\_\_\_/s/  
RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Monte Brown, MD  
Vice President of Administration and Secretary  
Duke University Health System  
107B Davison Building  
Durham, NC 27710

**Re: Revocation of EUA**

Dear Dr. Brown:

This letter is in response to Duke University Health System's (Duke's) request dated April 9, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor (hereafter referred to as "Duke Decontamination System") issued on May 7, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Duke will no longer make the Duke Decontamination System available for the authorized emergency use. In its request, Duke confirmed that it has ceased operation of all Duke Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Duke has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Duke's EUA for the Duke Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Duke Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Duke to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Peter Kalkbrenner  
Steriluent, Inc.  
1400 Marshall Street NE  
Minneapolis, MN 55413

**Re: Revocation of EUA**

Dear Mr. Kalkbrenner:

This letter is in response to Steriluent, Inc.'s (Steriluent's) request dated April 15, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Steriluent HC 80TT Hydrogen Peroxide Sterilizer (hereafter referred to as "Steriluent Decontamination System") issued on April 20, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Steriluent will no longer make the Steriluent Decontamination System available for the authorized emergency use. In its request, Steriluent confirmed that it has ceased operation of all Steriluent Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Steriluent has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Steriluent's EUA for the Steriluent Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Steriluent Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Steriluent to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration





June 30, 2021

Ms. Nancy Havill  
Manager, Infection Prevention Ambulatory Services  
Yale New Haven Health System  
20 York Street  
New Haven, CT 06504

**Re: Revocation of EUA**

Dear Ms. Havill:

This letter is in response to Yale New Haven Health System's (Yale's) request dated April 16, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Yale New Haven Health FFR Decontamination System (hereafter referred to as "Yale Decontamination System") issued on January 15, 2021. Yale will no longer make the Yale Decontamination System available for the authorized emergency use. In its request, Yale confirmed that it has ceased operation of all Yale Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Yale has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Yale's EUA for the Yale Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Yale Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Yale to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration





June 30, 2021

Dr. Brodbeck  
Senior Director, Regulatory Affairs  
STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060

**Re: Revocation of EUA**

Dear Dr. Brodbeck:

This letter is in response to STERIS Corporation's (STERIS's) request dated May 13, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the V-PRO 1 Plus, V-PRO maX, V-PRO maX2, V-PRO 60, and V-PRO s2 models of the vaporized hydrogen peroxide (VHP) low temperature sterilization systems (hereafter referred to as "STERIS Decontamination Systems") issued on April 9, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. STERIS will no longer make the STERIS Decontamination Systems available for the authorized emergency use. In its request, STERIS confirmed that it has ceased operation of all STERIS Decontamination Systems sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because STERIS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of these systems, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes STERIS's EUA for the STERIS Decontamination Systems, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the STERIS Decontamination Systems are no longer authorized for emergency use by FDA.

FDA encourages STERIS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Dr. Brodbeck  
Senior Director, Regulatory Affairs  
STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060

**Re: Revocation of EUA**

Dear Dr. Brodbeck:

This letter is in response to STERIS Corporation's (STERIS's) request dated May 13, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the AMSCO Medium Steam Sterilizers and the STERIS STEAM Decontamination Cycle in AMSCO Medium Steam Sterilizers as the cycle for decontamination of compatible N95 respirators (hereafter referred to as "STERIS Steam Decontamination System") issued on May 21, 2020, and revised and reissued on January 21, 2021. STERIS will no longer make the STERIS Steam Decontamination System available for the authorized emergency use. In its request, STERIS confirmed that it has ceased operation of all STERIS Steam Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because STERIS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes STERIS's EUA for the STERIS Steam Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the STERIS Steam Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages STERIS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Moira Barton-Varty, RAC  
Senior Principal Regulatory Affairs  
Stryker Sustainability Solutions  
1810 West Drake Drive  
Tempe, AZ 8528

**Re: Revocation of EUA**

Dear Ms. Barton-Varty:

This letter is in response to Stryker Sustainability Solution's (SSS's) request dated May 25, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Stryker Sustainability Solutions VHP N95 Respirator Decontamination System (hereafter referred to as "SSS Decontamination System") issued on May 27, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. SSS will no longer make the SSS Decontamination System available for the authorized emergency use. In its request, SSS confirmed that it has ceased operation of all SSS Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because SSS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes SSS EUA for the SSS Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the SSS Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages SSS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Joseph R. Haywood  
Assistant Vice President of Regulatory Affairs  
o/b/o F. Claire Hankenson, DVM, MS, Director  
Campus Animal Resources and University Veterinarian  
Michigan State University Animal Care Program  
4000 Collins, Suite 120  
Lansing, MI 48910

**Re: Revocation of EUA**

Dear Mr. Haywood:

This letter is in response to Michigan State University Animal Care Program's (MSU's) request dated May 27, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the MSU System for Decontaminating Compatible N95 Respirators (hereafter referred to as "MSU Decontamination System") issued on July 24, 2020, and revised and reissued on January 21, 2021. MSU will no longer make the MSU Decontamination System available for the authorized emergency use. In its request, MSU confirmed that it has ceased operation of all MSU Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because MSU has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes MSU's EUA for the MSU Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the MSU Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages MSU to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration





June 30, 2021

Ms. Carolyn Shelton  
VP, Global Regulatory & Medical Affairs, Product Stewardship  
Advanced Sterilization Products, Inc.  
6920 Seaway Blvd.  
Everett, WA 98203

**Re: Revocation of EUA**

Dear Ms. Shelton:

This letter is in response to Advanced Sterilization Products, Inc. (ASP) STERRAD's request dated June 4, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the ASP STERRAD 100S, NX, and 100NX Sterilization Systems (hereafter referred to as "ASP STERRAD Decontamination Systems") issued on April 11, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. ASP STERRAD will no longer make the ASP STERRAD Decontamination Systems available for the authorized emergency use. In its request, ASP STERRAD confirmed that it has ceased operation of all ASP STERRAD Decontamination Systems sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ASP STERRAD has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of these systems, when used for their emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes ASP STERRAD's EUA for the ASP STERRAD Decontamination Systems, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the ASP STERRAD Decontamination Systems are no longer authorized for emergency use by FDA.

FDA encourages ASP STERRAD to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Mr. Brent Hart  
Technical Safety Services LLC  
620 Hearst Avenue  
Berkeley, CA 94710

**Re: Revocation of EUA**

Dear Mr. Hart:

This letter is in response to Technical Safety Services LLC's (TSS's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the 20-CS Decontamination System (hereafter referred to as "TSS Decontamination System") issued on June 13, 2020, and revised and reissued on January 21, 2021. TSS will no longer make the TSS Decontamination System available for the authorized emergency use. In its request, TSS confirmed that it has ceased operation of all TSS Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because TSS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes TSS's EUA for the TSS Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the TSS Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages TSS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Mr. Jeffrey J. Morris  
President  
Roxby Development, LLC  
102 Carmel Road  
Wheeling, WV 26003

**Re: Revocation of EUA**

Dear Mr. Morris:

This letter is in response to Roxby Development, LLC's (Roxby's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Zoe-Ann Decontamination System (hereafter referred to as "Roxby Decontamination System") issued on October 20, 2020. Roxby will no longer make the Roxby Decontamination System available for the authorized emergency use. In its request, Roxby confirmed that it has ceased operation of all Roxby Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Roxby has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Roxby's EUA for the Roxby Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Roxby Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Roxby to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Mr. Yasser Estafanous  
Director for Regulatory Affairs and Quality Assurance  
3B Medical, Inc.  
203 Avenue A NW, Suite 300  
Winter Haven, FL 33881

**Re: Revocation of EUA**

Dear Mr. Estafanous:

This letter is in response to 3B Medical, Inc.'s (3B Medical's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Lumin LM3000 Bioburden Reduction UV System (hereafter referred to as "3B Medical Bioburden Reduction System") issued on December 3, 2020. 3B Medical will no longer make the 3B Medical Bioburden Reduction System available for the authorized emergency use. In its request, 3B Medical confirmed that it has ceased operation of all 3B Medical Bioburden Reduction System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because 3B Medical has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes 3B Medical's EUA for the 3B Medical Bioburden Reduction System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the 3B Medical Bioburden Reduction System is no longer authorized for emergency use by FDA.

FDA encourages 3B Medical to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration





June 30, 2021

Mr. Raghu Jainapur  
Vice President, Regulatory Affairs, Global Healthcare  
Ecolab Inc.  
1 Ecolab Place  
St. Paul, MN 55102

**Re: Revocation of EUA**

Dear Mr. Jainapur:

This letter is in response to Ecolab Inc.'s (Ecolab's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Bioquell Technology System (hereafter referred to as "Ecolab Decontamination System") issued on December 4, 2020. Ecolab will no longer make the Ecolab Decontamination System available for the authorized emergency use. In its request, Ecolab confirmed that it has ceased operation of all Ecolab Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Ecolab has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Ecolab's EUA for the Ecolab Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Ecolab Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Ecolab to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration



June 30, 2021

Ms. Susanne Galin  
Stryker Instruments  
2505 Avenue Dalton  
Quebec, QC G1P3S5 Canada

**Re: Revocation of EUA**

Dear Ms. Galin:

This letter is in response to Stryker Instruments' (Stryker's) request dated June 8, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Stryker Instrument's Sterizone VP4 Sterilizer N95 Respirator Decontamination Cycle (hereafter referred to as "Stryker Decontamination System") issued on April 14, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Stryker will no longer make the Stryker Decontamination System available for the authorized emergency use. In its request, Stryker confirmed that it has ceased operation of all Stryker Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Stryker has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Stryker's EUA for the Stryker Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Stryker Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Stryker to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Dated: August 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

